

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent application of )  
BAJAJ et al. ) Examiner: C. R. Lea  
Serial No. 10/574,666 ) Art Unit: 1619  
Filed: April 4, 2006 ) Atty. Dkt. No.: 125139.0101  
For: A NOVEL DRUG DELIVERY )  
SYSTEM FOR PROTON PUMP )  
INHIBITOR AND PROCESS )  
THEREOF )

**DECLARATION UNDER 37 C.F.R. §1.132**

Commissioner of Patents  
P.O. Box 1540  
Alexandria, VA 22313-1450

Sir:

In response to the Office Actions dated March 22, 2010, and to supplement the Declaration Under 37 C.F.R. § 1.132 filed December 15, 2009 ("December Declaration"), the undersigned declares as follows:

1. I, Bharat Babulal Shah, a citizen of India, residing at the below-referenced address, am an inventor of the above-identified patent application. I am a quality assurance general manager at Lyka Labs Limited. I received my Bachelor of Pharmacy from Gujarat University and have over thirty (30) years of experience in pharmaceutical analysis, including quality and reliability testing, data analysis, and GMP/GLP monitoring.
2. The data described in the December Declaration was prepared to show superiority of the present composition (containing rabeprazole to alkaline compound ratio of 1:0.359) when compared to the composition of Doan et al. (containing rabeprazole to alkaline compound ratio of 1:1). Thus, the two compositions (composition A and composition B) were made identically except for the amount of alkaline compound to show side by comparison. The "other ingredient claimed by the present invention" is mannitol; the alkaline compound is sodium hydroxide. Water for injection was added for reconstitution.
3. The amounts of rabeprazole were assayed using high performance liquid chromatography (HPLC). The protocol for the assay is attached as Appendix A. According to the protocol, the relative standard deviation of six replicate injections is not more than 2%.

4. Therefore, it remains my opinion that the data presented in December Declaration shows that by changing that ratio in accordance with the present invention, it is possible to significantly improve the stability of rabeprazole. That improvement is significantly and unexpected from the disclosure of the prior art.

5. The undersigned hereby declares that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and that such willful false statements may jeopardize the validity of the application of any patent issued thereon.

Respectfully submitted,

Date: 19<sup>th</sup> Aug. 2010

Bharat Babulal Shah

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